

EXHIBIT NO.

17

Acute flaccid myelitis, the polio-like syndrome leaving some children partially paralyzed. NBC News

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By Maggie Fox

The Centers for Disease Control and Prevention says it doesn't know what's causing a sudden rise in cases of a frightening, polio-like condition that leaves children paralyzed or with weakened limbs.

The No. 1 suspect had been a virus called enterovirus D68, or EV-D68. In 2014, a wave of cases of acute flaccid myelitis coincided with outbreaks of EV-D68 across the country.

But the CDC says it has not consistently found EV-D68 in confirmed cases since then. Officials say they're looking at a couple of possible causes.

However, doctors who have been studying children affected by acute flaccid myelitis say they have gathered a growing body of evidence that EV-D68 is the main cause,

and that the virus may have changed in recent years in ways that make the paralyzing side-effects more likely.

They've documented an increase in cases of EV-D68 surrounding outbreaks of acute flaccid myelitis. Experiments have also shown that EV-D68 can invade nerve tissue, including the spine, and there's also evidence of genetic changes in the virus itself.



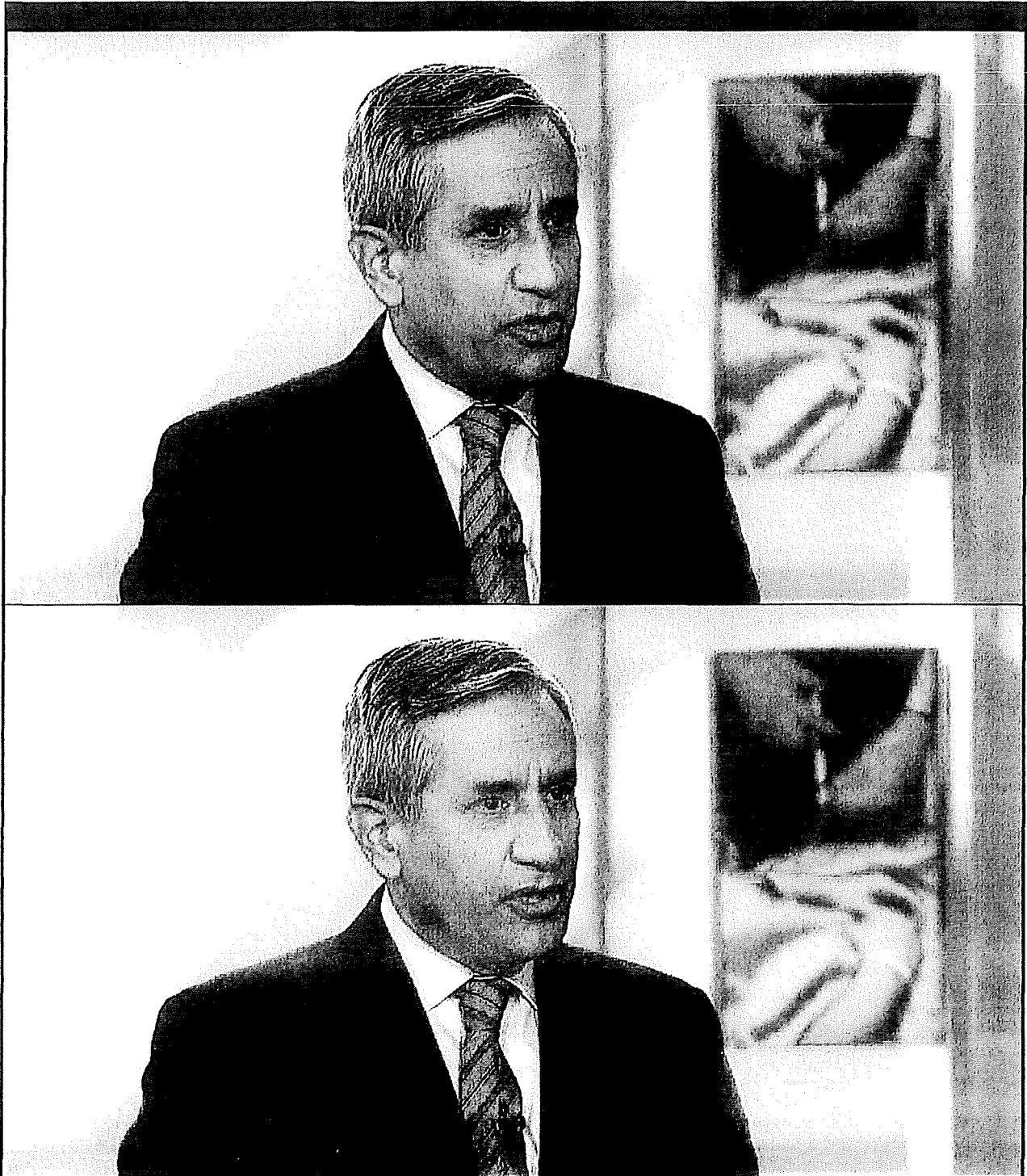
HEALTH

Doctors are struggling to find a cause of this paralyzing condition

A team of academic researchers have formed their own network to try to determine why a very few children develop the paralyzing syndrome from a virus that is harmless in more than 99 percent of those it infects.

“It’s puzzling that four years later CDC has not confirmed the etiology of these cases,” said Dr. Ali Khan, dean of the University of Nebraska Medical Center College of Public Health.

“Continuing to frame this as a mystery after so many years doesn’t do the public health any justice,” added Khan, a former director of CDC’s Office of Public Health Preparedness and Response.



155 AFM cases under investigation, CDC confirms

State health departments have reported at least 191 possible cases of acute flaccid myelitis to the CDC this year, and the

agency says it has confirmed 72 of them. Other cases may also be related to viral infection, but they don't have the same precise symptoms of acute flaccid myelitis, which include sudden onset and specific damage to the spinal cord.

What's clear to the doctors who have treated many of the cases is that some virus is responsible, and that most cases are likely due to EV-D68.

"I think we are seeing the emergence of a new polio-like paralytic disease. Its pattern and most of the evidence that we have suggests that it is likely a virally caused disease," Dr. Ken Tyler, a neurologist at the University of Colorado School of Medicine, told NBC News.



The long road to recovery from acute flaccid myelitis
Some kids never recover.

"I think the leading candidate is enteroviruses in general and EV-D68 in particular."

Many different viruses circulate all at the same time, and one strain will be common one season and another strain the next.

Increases in cases of acute flaccid myelitis were documented in 2014, 2016 and now in 2018. The CDC said there's not much evidence that EV-D68 cases also increased in 2016.

But Dr. Gregory Storch of Washington University in St. Louis and colleagues found an outbreak of EV-D68 in their region in 2016 that they said would have been missed if they had not actively looked for it in samples from children turning up in the St. Louis Children's Hospital with respiratory symptoms.

"It does seem that enterovirus D68 has been present every other year," Storch said. "Each of those times, there has been an increase in acute flaccid myelitis that occurred at the same time as the EV-D68 activity."

Dr. Kevin Messacar of Children's Hospital Colorado and colleagues similarly found an increase in EV-D68 cases in Colorado in 2016.

And Guiqing Wang, a pathologist at New York Medical College, and colleagues did genetic testing to identify a new strain of EV-D68 that had circulated in both 2014 and 2016. It caused an outbreak of 160 confirmed cases in the Lower Hudson Valley of New York in 2016, they reported.



HEALTH

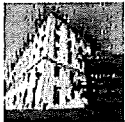
Hand, foot and mouth disease has college students hiding in dorms

“It looks like the new strains are better able to affect human motor neuron-like cells than older strains,” said Tyler.

It wasn’t just the U.S.: European researchers reputed 29 cases of EV-D68 infection in children and adults with acute flaccid myelitis in 2016.



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Tyler and colleagues infected mice with EV-D68 and showed it could affect the nervous system. “We know that enterovirus D68 in mice can produce an illness very much like what you see in children,” Tyler said. “You can see enterovirus particles in the motor neurons.”

It's not proof, Tyler said. "It means you have established that it is plausible that a virus does behave in this way," he said.

What's missing is the surveillance needed to show that outbreaks of EV-D68 were large enough to account for the increases in cases of AFM in 2016 and now in 2018, and that most patients with AFM were also infected with EV-D68.

TEST QUICKLY TO CATCH THE VIRUS

There's also a need to find out what other viruses might be causing cases. Messacar noted that a virus called EV-A71 caused outbreaks of hand, foot and mouth disease this fall in Colorado, and that virus has also been linked to neurological effects.



What is acute flaccid myelitis?

That means doctors need to act more quickly to test kids who begin showing signs of weakness or paralysis. That might not be the first priority if a child comes to the emergency room with trouble breathing or an arm that suddenly doesn't work.

But a virus can cause damage to the nervous system and then disappear when the immune response kicks in — leaving a crime scene with little evidence of the perpetrator. That adds to the mystery.

“Other data from 2014 suggest that the faster you did the swabs, the higher the yield was,” Tyler said. After a week or so, it was hard to find any virus in the patients, he said.

"One of the things we need to do more of going forward is active surveillance," Messacar said.

It's also possible that the damage is not directly caused by the virus, but by an abnormal immune response to the infection. That makes it even more important to catch the virus in the act.

A few days can make all the difference, said Dr. Aaron Milstone, a pediatrician at Johns Hopkins Medicine who is part of an informal network of researchers trying to get to the bottom of what has caused the increase in AFM cases.

by Taboola

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“This is a scary phenomenon that we are seeing, but it is uncommon. It is very unlikely that one’s child will develop this.”

They’re telling doctors to get tests as quickly as possible from patients, including respiratory swabs, stool samples and spinal taps. “These are common areas where we would find enteroviruses,” Milstone said.

“As soon as you have that presentation of weakness or paralysis, that’s when you should get that testing done — immediately. Don’t wait a few days.”

Milstone says his network is also trying to figure out what it is about the patients that makes them susceptible to paralysis, possibly some genetic predisposition.

“We have been recruiting patients for four years now for a genetics study and it is really hard when patients are all over the country,” he said.

“We have sent emails to institutions across the county and say, ‘hey, do you know of anyone?’”

None of this means parents need to worry if their child develops a cold. “We don’t want people rushing to the pediatrician just because their kid has a stuffy nose,” Milstone said.

“This is a scary phenomenon that we are seeing, but it is uncommon. It is very unlikely that one’s child will develop this.”



Maggie Fox

Maggie Fox is a senior writer for NBC News and TODAY, covering health policy, science, medical treatments and disease.